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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/553,298

12/01/2005

Nicholas Barden

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22428 7590 09/02/2009
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EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

09/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/553,298	Applicant(s) BARDEN ET AL.	
	Examiner Michael Pak	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 24-30, 32-34 and 36-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-22, 24-30, 32-34, 39 and 44-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-38 and 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2-12-09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Claims 36-38 and 40-43 are examined below. Claims 1-22, 24-30, 32-34, 39, and 44-56 are withdrawn. Claims 23, 31, 35, are cancelled.
2. Applicant's arguments filed May 28, 2009, have been fully considered but they are not found persuasive.
3. This application contains claims 1-22, 24-30, 32-34, 39, and 44-56 drawn to an invention nonelected with traverse in the reply filed on October 10, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 36-38 and 40-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Franco et al. (US 2004/0229262).

Franco et al. teach a method of administering agonist for treatment of affective disorders (paragraph 123, 125-127, 639 and 677) and teach that BzATP is an agonist. Franco et al. teach depression and treatment of depression (paragraph 125-127, 135 and 639). The beta-adrenergic receptor modulator is optional. BzATP inherently modulates P2X7R activity.

Applicants argue that Franco et al. does not teach a method of treating major depression comprising administering BzATP to a subject in need thereof. However, page 124 teaches a method of treating with modulators such disorders as depression and P2X activity disorders (paragraph 639; page 134, second column, last paragraph). Franco teaches BzATP as agonist modulator of P2X7 (paragraph 0677). Thus Franco et al. teaches treatment of depression with BzATP.

Applicants argue that Franco et al. HBMYP2X7v variant lacks the amino acid for ATP binding thus teaches away from the invention. However, the teaching of Franco includes modulators including BzATP explicitly stated as modulators and treatment of depression or P2X activity disorders. Furthermore, Franco et al. teach using HBMYP2X7v variants which encompasses P2X7. Thus, Franco et al. does not explicitly teach away from the claimed invention.

Applicants argue that Franco et al. does not demonstrate that splice variant HBMYP2X7v is relevant in individuals suffering from major depression. However, the teaching of Franco includes modulators including BzATP explicitly stated as modulators

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and treatment of depression or P2X activity disorders. Furthermore, Franco et al. teach using HBMYP2X7v variants which encompasses P2X7. Thus, Franco et al. appears to indicate that treatment of depression is relevant to using HBMYP2X7v variants which encompasses P2X7.

Applicants argue that Franco et al. fails to provide evidence that an agonist of P2X7 is needed for treatment of major depression citing art which indicates that at the time of the invention antagonists were used to treat affective disorders. However, the teaching of Franco includes modulators including BzATP explicitly stated as modulators and treatment of depression or P2X activity disorders. Furthermore, Franco et al. teach using HBMYP2X7v variants which encompasses P2X7. Thus, Franco et al. teaches treatment of depression is relevant to using HBMYP2X7v variants which encompasses P2X7 with the evidence available at the time of the invention.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 571-272-0879. The examiner can normally be reached on 8:00 - 2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael Pak/
Primary Examiner, Art Unit 1646